This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 51-F-0024
CUSTOMER NUMBER: 12776

FORM APPROVED
OMB NO. 0579-0036

Center For Biologics Evaluation & Research
29 Lincoln Drive
Bethesda, MD 20852

Telephone: (b)(6), (b)(7)c

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (**Attach additional sheets if necessary or use APHIS Form 7023A**)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	0	341	151	16	508
7. Hamsters	0	120	6	0	126
8. Rabbits	0	82	0	0	82
9. Non-human Primates	25	55	7	0	87
10. Sheep	0	8	0	0	8
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets	0	15	0	0	15

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATU (b)(6), (b)(7)c

DATE SIGNED 11/27/01

APHIS FO
(AUG 91)

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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1. **Registration Number:** 51-F-0024

2. **Number of animals used in this study subject to column E listing:** 16

3. **Species (common name) of animals used in this study:** Guinea Pigs

4. **Explain the procedure producing pain and/or distress.**

   ASP# 89-32. This is a potency test that evaluates the presence of sufficient protective antigen in toxiods manufactured to prevent tetanus and diphtheria in humans. It is performed by CBER as a lot release test to verify adequate protection to the U.S. population by vaccines licensed in the U.S. Animals are injected with a combination of toxin and protective antibodies and survival is determined out to 7 days. Protected pigs show no signs, but control animals and inadequately protected animals will develop signs of disease and proceed to death rapidly without the benefit of euthanasia. Historically, 10 % of the total number of animals used have died as a result of toxin administration and therefore have fallen under column E.

5. **Provide scientific justification why paid and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below).**

   As required by the Minimum Standards (which are the precursors to the CFR) animals which become sick before 96 house cannot be euthanized. After 96 hours and up until the end of the test of 7 days, any animals showing signs of disease can be euthanized. There is no in vitro alternative for potency testing these two components of the U.S. Childhood Vaccination Program.

6. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):**
   This test is required by the FDA Minimum Standards Requirements.